

Application No.: 10/664,764
Filing Date: September 17, 2003
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EXHIBIT I

Declaration of Dr. Andreas Burgard Under 37 C.F.R. §1.132

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, **ANDREAS BURGARD** declare and state that:

1. I am a resident of the Federal Republic of Germany.
2. I am a citizen of the Federal Republic of Germany.
3. I am a chemist having received a university degree in chemistry (equivalent to MS in chemistry) from Johannes Gutenberg University in Mainz, Germany.
4. Since 1998 I have been employed with Nutrinova Nutrition Specialties & Food Ingredients, GmbH ("Nutrinova"). My research for Nutrinova has generally focused on artificial sweeteners. For the past 6 years my work has focused on products incorporating the potassium salt of acesulfame, commonly referred to as acesulfame - k ("AcK").
5. I consider myself qualified by my knowledge of chemistry and by my years of experience in these technical fields for more than 12 years.
6. I am a co-inventor of the above-captioned United States Patent Application, i.e. application Serial No. 10/664,764, and therefore have personal knowledge of its subject matter.
7. I have read and understand the non-final Official Action mailed on June 2, 2004 ("the Office Action").

8. I understand that Claims 1 through 3 and 6 stand rejected within the above-referenced application as being unpatentable over the combination of European Patent Application 0122400 to Nakajima ("Nakajima"), United States Patent No. 5,298,648 to Ebisawa et al. ("Ebisawa") and United Kingdom Patent Application 1297741 to Ninomiya et al. ("Ninomiya") in view of WIPO Publication No. 99/04822 to Ledniczky et al ("Ledniczky") and WIPO Publication No. 00/12067 to Rayburn ("Rayburn").
9. Each of the primary references, i.e. Nakajima, Ebisawa and Ninomiya, are merely directed to conventional mixtures of individual chemicals.
10. In contrast, the claimed invention is directed to reacted chemical compounds and not just mixtures of various components in solution. These compounds are made from an amino acid and at least one sweetener. Contrary to mixtures, the new compounds according to the invention have homogeneous, unique properties, e.g. melting points, crystal structure or NMR-peaks (to name just a few). In the new compounds the amino acid and sweetener are present in a discrete, stoichiometric molecular ratio of either 1:1 or 1:2 and the sweetener may advantageously be selected from one or more of acesulfame, aspartame, alitame, cyclamate, glycyrrhizin, neotame, saccharin, gluconic acid and gluconate.
11. Conventional mixtures formed from artificial sweeteners and amino acids can separate back out into their component parts, leading to unpleasant inhomogeneities in the taste of the resulting foodstuffs.
12. Surprisingly, it was determined that two quite dissimilar compounds, i.e. amino acids and artificial sweeteners, can be chemically reacted to produce new compounds, in this case salts. These new compounds

eliminate the problem of component separation inherent within the heretofore known mixtures. Bearing in mind that within such complex chemical structures as amino acids and artificial sweeteners even slight modifications such as replacement of e.g. a hydrogen by a methyl group may yield in total loss of some of the compounds characteristic properties e.g. sweetness or biological activity, it was highly surprising that each of the starting compounds properties could be maintained in the newly formed compounds.

13. Further, although each of the starting materials for the new compounds are known to potentially impart unpleasant tastes (amino acids) and/or aftertastes (artificial sweeteners), their reaction product, i.e. the new salts exhibit a pure, sweet taste.
14. In contrast to the opinion urged within the Office Action, the claimed salt formation to me was quite unexpected, as it would not have occurred upon simple mixing of e.g. a sweetener salt with an amino acid in solution. In general, water soluble salts split into their respective cations and anions upon dissolution in water. Therefore, what would have happened in the mixtures known in the art (e.g. Ninomiya et al; Na-saccharin and tryptophan) is that saccharin⁻ and Na⁺ ions would have been formed and that tryptophan is dissolved as neutral molecule. No further reaction would have occurred. Even if the water would have been removed - which is not disclosed in the prior art – no salt of tryptophan and Na-saccharin would have formed.
15. Other mixtures shown in the prior art (e.g. Ebisawa et al.) do not even form ions upon dissolution in water. Ebisawa et al. dissolve aspartame (a sweetener) and L-aspartyl-L-tyrosine (an amino acid) in water (c.f. Ebisawa et al., examples). They isolate the sweetener (aspartame) as a pure

product. There is no report of any other product formed, let alone a sweetener-amino-acid salt.

16. The ionic sweeteners disclosed in the prior art are in the form of an artificial sweetener salt, primarily the sodium or potassium salt. The cited prior art does not teach or suggest sweetener acids.
17. It is to be noted that in the present invention the sweetener-amino acid salts are advantageously formed using the "sweetener acids" (like protonated acesulfame, also referred to as AcH) as a starting material and not the sweetener salts (like AcK). It is my experience that sweetener-amino acid salts would not even have formed if the corresponding artificial sweetener salts, such as the sodium or potassium artificial sweetener salts noted in Ninomiya and Nakajima respectively, would have been employed as reactants.
18. The Examiner's statement that Applicant uses well-known components for their art-recognized function is not understood. The art-recognized function of a sweetener would be to sweeten something; the art-recognized function of an amino acid would be to provide for peptide/protein units. None of these art-recognized functions is used in the present invention. The function of the sweeteners and the amino acids in the present invention was to form suitable starting compounds for a reaction in which new compounds are formed.
19. Further, the fact that upon hydrolysis, such as encountered during ingestion, the claimed compounds revert back into sweeteners and amino acids has to be considered surprising. With the same level of likelihood they could as well have been cleaved into totally different radicals or even not at all.

20. None of the cited references, alone or in combination teach or suggest that amino acids and artificial sweeteners can be chemically reacted to produce recoverable salts.
21. The cited primary references instead evidence conventional wisdom at the time this invention was made that indicated the formation of a solution upon the dissolution of an artificial sweetener and a secondary component within a solvent.
22. Ledniczky and Rayburn, directed to pharmaceutical compounds, do not cure the deficiencies within the primary references.
23. There would have been no motivation to form the claimed amino acid salts, based on the compounds of Ledniczky and Rayburn, which have altogether different chemical structures and utilities from the claimed compounds.
24. The chemical arts are unpredictable, particularly regarding the expected efficacies of various compounds. The efficacies of Rayburn or Ledniczky can thus not be imputed to the claimed amino acid-based salts, particularly in light of the structural dissimilarities between Rayburn or Ledniczky's drugs and the recited amino acids.
25. Not any and all combinations of sweeteners and secondary components form salts, as clearly evidenced by the mixtures formed by the primary references. Therefore, one skilled in the art would not think that the teachings of Ledniczky or Rayburn would be transferable to amino acids. Rather, one would have expected that mixtures such as as those noted in the primary references would form.

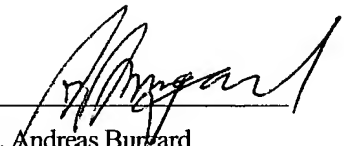
26. Further, there is no similarity in utility between Rayburn or Ledniczky and the claimed amino acid-based salts. Rayburn and Ledniczky are each directed to various families of drugs. In contrast, the claimed compounds are primarily used as food additives.
27. Moreover, if Rayburn and Ledniczky would indeed serve as a generic motivation to form salts of a sweetener and a drug because the sweetener would cover the bitter taste of the drug, why then does Nakajima provide for the exact opposite teaching? Nakajima uses amino acids to mask the bitter taste of AcK (c.f. Nakajima Abstract). Based on the teachings of Nakajima there would have been no motivation to have taken a bitter tasting component, i.e. AcK, and combine it with another known bitter component, i.e. amino acid, to form a sweet tasting compound.
28. In fact, the unexpectedly sweet tasting compounds of the claimed invention are a good example of the unpredictability of chemistry. Generally, properties of new chemical compounds cannot be predicted from their starting compounds. Same here.
29. In addition, there would have been no motivation to have combined the references as none of the cited references addresses the particular issue solved by the claimed invention, i.e. the taste inhomogenieties inherent in conventional sweetened amino acid mixtures. As the references do not even recognize the issue, they most certainly do not recognize salt formation as a result effective variable in resolving that issue.
30. Accordingly, there would have been no motivation to have combined these references.
31. However, even if the references were combined the recited salt would not be formed. The primary references disclose mixtures incorporating either

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non-ionized artificial sweetener or sodium or potassium salts of artificial sweeteners. The secondary references are directed to drugs. Accordingly, none of the references teach or suggest recited salts formed from a basic-reacting amino acid with at least one acidic-reacting artificial sweetener.

32. I thus respectfully submit that the claimed invention is patentable in light of the art of record, considered either alone or in combination.
33. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

03.11.04
Date


Dr. Andreas Burgard